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DEC 05 2006

Appl. No. : 10/783,783
Filed : February 20, 2004

REMARKS

By way of summary, Claims 1-30 are pending in this application. Claims 19 and 20 have been amended. In the outstanding Office Action of September 13, 2006, the Examiner acknowledged certain Information Disclosure Statements, objected to Claim 20 and Claim 26, and rejected Claims 1-30 under 35 U.S.C. 103(a).

1. Information Disclosure Statements

Applicants recognize the Examiner's acknowledgement of the information disclosure statements (IDS) submitted on April 26, 2004, May 2, 2005, and August 19, 2005. However, Applicants also sent an IDS on September 1, 2006 listing seven references and enclosing one reference which is listed on the application transaction history on PAIR on September 5, 2006. Applicants have attached a courtesy copy of the previous IDS for the Examiner's convenience. Applicants respectfully request the Examiner's acknowledgement of the September 1, 2006 IDS.

Furthermore, Applicants are submitting a Supplemental IDS with this Office Action response listing two references. Applicants respectfully request the Examiner's acknowledgement of the accompanying Supplemental IDS.

2. Claim Objections**Claim 20 and/or 29**

The outstanding Office Action objected to Claim 20 citing an informality: "On line 2 of Claim 29 it reads 'the coil' and should instead read --a coil--." Claim 29 recites, "The assembly of Claim 20, wherein the coil is sized to extend through a septum primum and a septum secundum of a patent foramen ovale." Use of the term "the coil" in Claim 29 appears to have proper antecedent basis to the term "coil" as provided in Claim 20, from which Claim 29 is a dependent claim. Applicants assume that the Examiner may have intended to recite to Claim 20 in stating "On line 2 of Claim 29" instead of Claim 29. If this assumption is incorrect, please notify Applicants in the next Office Action. In the interest of expediting prosecution, Applicants have amended Claim 20 to recite, in part, "a loading portion adapted to releasably engage a proximal end of a coil" instead of "a loading portion adapted to releasably engage a proximal end of the coil." Therefore Applicants respectfully request that Examiner withdraw this rejection.

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Claim 26

The outstanding Office Action objected to Claim 26 under 37 CFR 1.75(c) "as being of improper dependent form for failing to further limit the subject matter of a previous claim." The Examiner cited "Claim 26 recites 'comprising a coil having a proximal end releasably engaging the loading portion and a distal end releasably engaging the tissue piercing structure' when the same limitation is recited in lines 2-5 of Claim 1."

Applicants respectfully submit that Claim 26, which is an apparatus assembly dependent claim of Claim 20, is not a dependent claim of Claim 1, which is a method claim. Claim 26 establishes its dependent claim status in reciting, "The assembly of Claim 20, further comprising a coil having a proximal end releasably engaging the loading portion and a distal end releasably engaging the tissue piercing structure." The method steps disclosed in Claim 1 include references to a coil, but that coil has no "proximal end releasably engaging the loading portion and a distal end releasably engaging the tissue piercing structure."

Alternatively, the Examiner may have intended to recite that Claim 26 improperly limited the subject matter of Claim 20. If this assumption is incorrect, please notify Applicants in the next Office Action. Applicants respectfully submit that Claim 26 properly further limits the subject matter of Claim 20. The elements of Claim 20 include an assembly comprising a loading portion and a tissue piercing structure. The loading portion is "adapted to releasably engage a proximal end of the coil" and the tissue piercing structure is "adapted to releasably engage a distal end of the coil." Claim 26, however, adds a new structural element: the coil itself. This coil has "a proximal end releasably engaging the loading portion and a distal end releasably engaging the tissue piercing structure." The addition of the element of the coil in Claim 26 further limits the subject matter of the independent Claim 20. Therefore Applicants respectfully request that Examiner withdraw this rejection.

3. § 103(a) Claim Rejections

- a. Claim 1 and dependent Claims 2-11 are not rendered obvious by Adams et al. (U.S. Pub. No. 20050119675);

The outstanding Office Action rejected Claims 1-11 under 35 U.S.C. §103(a) as being unpatentable over Adams et al. (U.S. Pub. No. 20050119675) in view of Figures 6-10, page 7,

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paragraphs 108 and 112. In particular, Claims 1, 2, 9, and 10 were rejected as unpatentable over Adams; Claims 3 and 4 were rejected as unpatentable over Adams in view of Johnson et al. (U.S. Pat. No. 6,485,504); Claims 5-7 were rejected as unpatentable over Adams in view of Laufer et al. (U.S. Pub. No. 20040193194); Claim 8 was rejected as unpatentable over Adams and Laufer in view of Johnson; and Claim 11 was rejected as unpatentable over Adams in view of Pierson, III (U.S. Pat. No. 6,663,633).

As indicated by the attached statement, the present application and the Adams reference were, at the time the invention was made, owned by, or subject to an obligation of assignment to, the same person. The subject matter of the present application was 100% owned by ev3 Sunnyvale, Inc. at the time the invention was made. The Adams reference was 100% owned by ev3, Inc. at the time the invention was made. ev3 Sunnyvale, Inc. was a 100% fully owned subsidiary of ev3, Inc. at the time the invention was made. MPEP § 706.02(1)(2) provides examples in which the inventions of 100% owned subsidiaries of parent companies are commonly owned by the parent company. Therefore, both the claimed invention of the present application and the Adams reference were, at the time the invention was made, commonly owned by the parent company, ev3, Inc.

Applications and references will be considered by the examiner to be owned by, or subject to an obligation of assignment to the same person, at the time the invention was made, if the applicant(s) or an attorney or agent of record makes a statement to the effect that the application and the reference were, at the time the invention was made, owned by, or subject to an obligation of assignment to, the same person. Thus, a statement, by itself, will be sufficient evidence. See the "Guidelines Setting Forth a Modified Policy Concerning the Evidence of Common Ownership, or an Obligation of Assignment to the Same Person, as Required by 35 U.S.C. 103(c)," 1241 OG 96 (Dec. 26, 2000).

Accordingly, in view of the attached statement, Applicants respectfully submit that the Adams reference be removed as prior art to this application. With the removal of the Adams reference, Applicants submit that Claims 1-12 are allowable.

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- b. Claim 12 and dependent Claims 13-19 are not rendered obvious by Adams et al. (U.S. Pub. No. 20050119675) in view of Pierson, III (U.S. Pat. No. 6,663,633);

The outstanding Office Action rejected Claims 12-19 under 35 U.S.C. §103(a) as being unpatentable over Adams in view of Pierson.

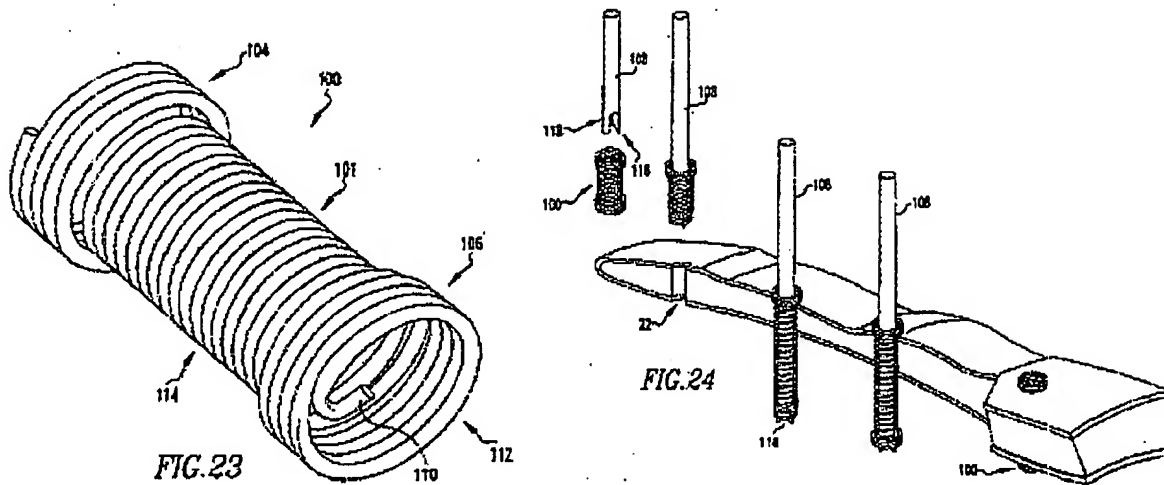
As stated above and in the attached statement, the present application and the Adams reference were, at the time the invention was made, owned by, or subject to an obligation of assignment to, the same person. The subject matter of the present application was 100% owned by ev3 Sunnyvale, Inc. at the time the invention was made. The Adams reference was 100% owned by ev3, Inc. at the time the invention was made. ev3 Sunnyvale, Inc. was a 100% fully owned subsidiary of ev3, Inc. at the time the invention was made. Accordingly, in view of the attached statement, Applicants respectfully submit that the Adams reference be removed as prior art to this application. With the removal of the Adams reference, Applicants submit that Claims 12-19 are allowable.

- c. Amended Claim 20 and dependent Claims 21-30 are not rendered obvious by Johnson et al. (U.S. Pat. No. 6,485,504) in view of Laufer et al. (U.S. Pub. No. 20040193194);

The outstanding Office Action rejected Claims 20-30 under 35 U.S.C. §103(a). In particular, Claims 20-21 and 24-26 were rejected as unpatentable over Johnson in view of Laufer; Claims 22-23 were rejected as unpatentable over Johnson and Laufer in further view of Kay (U.S. Pat. No. 5,662,683); Claims 27-28 were rejected as unpatentable over Johnson and Laufer in further view of Bolduc et al. (U.S. Pat. No. 5,582,616); Claim 29 was rejected as unpatentable over Johnson and Laufer in further view of Adams; and Claim 30 was rejected as unpatentable over Johnson and Laufer in further view of Pierson.

Johnson discloses a grommet 100 in the form of a spring 101 with a head flange 104 at its proximal end and a tail flange 106 at the tail end 110, or distal end, of the spring 101. Johnson Figs. 23-26, col. 18, ll. 60-67 and col. 19, ll. 1-47.

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Both the head flange 104 and the tail flange 106 have a greater diameter than the diameter of the hole 22 in the bone in which the spring 101 is to be inserted. The spring 101 has an elongated central portion 114 connected between the head flange 104 and the tail flange 106 which has an outer diameter slightly larger than the diameter of the hole 22 in the bone in which the spring 101 is to be inserted.

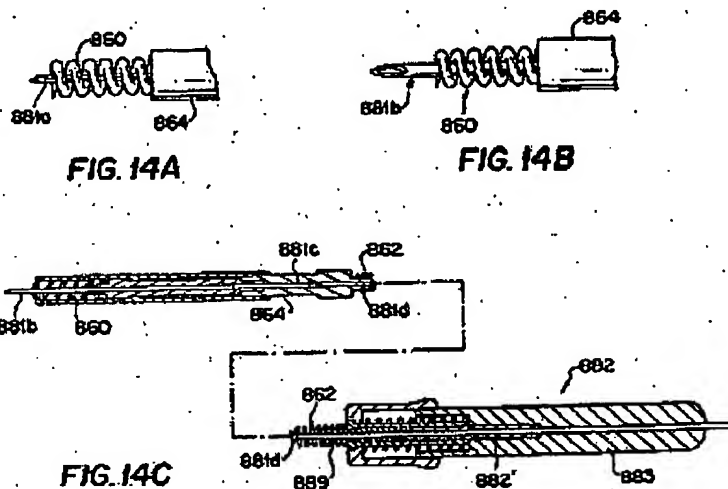
In order to insert the Johnson spring 101 into a hole 22, a pushing rod 108 with a diameter smaller than the inner diameter of the channel 112 of the grommet 100 and a slot 116 in its pushing end 118 (distal end) is used to engage with the tail end 110 (distal end) of the spring 101. Johnson col. 19, li. 9-36. To place the grommet 100 into the hole 22 in the bone, the slot 116 of the pushing rod 108 is inserted into the channel 112 of the grommet 100 and moved through the channel 112 of the grommet 100 until the slot 116 fits over the tail end 110 of the spring 101 which bends slightly inwards. Once the slot 116 grasps the end of the spring 101, the pushing rod 108 is twisted while the head flange 104 of the grommet 100 is held by friction between the lip of the head flange 104 and the surface surrounding the top of the hole 22, causing the tail flange 106 and the central portion 114 to narrow in diameter as the length of the grommet 100 extends under the twisting action.

The pushing rod 108 does not come in contact with the proximal end of the spring 101. With the outer diameter of the tail flange 106 and the central portion 114 now smaller than the inner diameter of the hole 22 in the bone, the tail flange 106 and central portion 114 are inserted with the pushing rod 108 into the hole 22 in the bone until the tail flange 106 extends beyond the

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bottom of the hole 22 in the bone. The pushing rod 108 is then backed out of the grommet 100 and the hole 22, resulting in the release of tension on the tail flange 106 portion and the central portion 114. When the tail flange 106 and the central portion 114 relaxes from the release of tension, the tail flange 106 expands to its nominal diameter, as does the central portion 114. The grommet 100 now in place in the bone, cannot be removed from the bone without considerable damage to the bone since the tail flange 106 and in the head flange 104 extend beyond the diameter of the hole 22, and the central portion 114 forms a friction fit with the inner diameter of the hole 22.

Laufer discloses a non-detachable coil 860 which acts as an anchor for a coupling member 864 which houses a needle 881a or a matter injector needle 881b, which can be advanced through the coil 860. Laufer Figs. 14A-14C, pg. 6, para. 0114 and 0115.



The coil 860 and needle 881a or a matter injector needle 881b are not connected at the distal end of the coil 860. The matter injector needle 881b has a metal tip 881c on a flexible, plastic tube 881d and is used in "bulking" procedures to augment tissue in a selected region by injecting a biocompatible material. See Laufer, para. 0115. In use, coil 860 acts to anchor needle 881b in the tissue to counteract pressure created by the material injection, which would tend to push needle 881b out of the tissue. Coil 860 never becomes detached from the coupling member 864, and is rotated back into the coupling member 864 after the tissue "bulking" material is delivered.

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Laufer states that a needle can also facilitate the initial engagement of coil 860 with the tissue, and is particularly applicable to situations in which coil 860 approaches the tissue surface at an angle. See Laufer, para. 0114. Laufer does not disclose any use of a needle to puncture tissue in order to create a passage for the insertion of a coil therethrough. Instead, the needle may be used to help maintain the axis of the coil 860 while the tip of the coil 860 creates its own separate puncture site in the tissue. Laufer's coil 860 is simply rotated into tissue much like a corkscrew without any axial loading to elongate or radially reduce the coil 860. As described in the Laufer specification, embodiments of the coil are used to position or engage with tissue only during procedures deploying a separate detachable fixation device, where the coil is in place temporarily while attached to the access instrumentation and is removed with the access instrumentation when some other medical procedure is complete. See Laufer para. 0095—0097. The coil is permanently attached to the coupling member by soldering, and is not detachable into the body. See Laufer para. 0105.

Applicants respectfully submit that it is improper to combine the teachings of the Johnson and Laufer references. First, it would not be obvious to combine a needle as found in Laufer with the method of Johnson because the Johnson reference is intended to be used with a pre-existing hole in a bone. As shown in Johnson Figure 24, the hole through which the Johnson grommet is placed already exists. Therefore, there would be no need for the needle to pierce through tissue. Moreover, as discussed above, the needle of Laufer is not even used to create a passage for the insertion of the coil.

Second, it would not be obvious to combine the implantable device of Johnson with a temporary anchoring system as disclosed in Laufer. The Laufer coil is not an implant which is detached into the body; it merely holds a coupling member near a tissue for injection of separate materials during a medical procedure. Accordingly, Applicants submit that one of skill in the art would not look to the Laufer reference to modify the device and method of Johnson.

Third, even if the references are combined in the manner proposed, the combination of the references still does not teach or suggest the limitations of the claimed invention. In contrast to the disclosure and teachings of Johnson and Laufer, amended independent Claim 20 recites "an assembly for delivering a coil through tissue in a patient, comprising: a loading portion adapted to releasably engage a proximal end of a coil; and a tissue piercing structure adapted to

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releasably engage a distal end of the coil, wherein the loading portion holds the coil relative to the tissue piercing structure to axially elongate and radially reduce the coil."

For example, the Johnson pushing rod 108 is not adapted to releasably engage a proximal end of a coil. Instead, the Johnson pushing rod 108 uses a slot 116 in its distal pushing end 118 to engage with the distal tail end 110 of the spring 101. The Johnson pushing rod 108 is not engaged with the proximal head flange 104 in any way; therefore it is impossible for the pushing rod 108 to impart any load to the proximal end of the spring 101 "to axially elongate and radially reduce the coil." The inner diameter of the head flange 104 is materially larger than the diameter of the central portion 114 of the spring 101, and the pushing rod 108 outer diameter is less than the inner diameter of the central portion 114. It is impossible for the pushing rod 108 to operate with the distal pushing end 118 while extending through the smaller diameter of the central portion 114 of the spring 101. Any loading of the head flange 104 of the grommet 100 is accomplished through friction between the lip of the head flange 104 and the bone surface surrounding the top of the hole 22, and not by a loading portion of any device.

The Laufer coupling member 864 may be attachable at a proximal end of the coil 860; however, because the coil cannot be detached from the coupling member, like Johnson, the coupling member does not releasably engage the proximal end of the coil. Moreover, the Laufer needle 881a or 881b does not engage the distal end of the coil. Therefore, the Laufer assembly does not in any way "axially elongate and radially reduce the coil."

Applicants respectfully submit that Johnson and Laufer fail to disclose or suggest the foregoing limitations of Claim 20. Accordingly, Applicants respectfully submit that independent Claim 20 is patentable over Johnson in view of Laufer and respectfully requests that the unpatentability rejection based on Johnson in view of Laufer be withdrawn.

Claims 21-30 depend from Claim 20 and further define the invention of Claim 20. For at least the reasons set forth above with respect to Claim 20, Applicants respectfully submit that Claims 21-30 are patentable over Johnson in view of Laufer. Claims 21-30 also are patentable over Johnson in view of Laufer in view of the additional limitations recited in each of the claims. Therefore, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of Claims 21-30 based on Johnson in view of Laufer.

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4. Conclusion

Applicants respectfully submit that the claims are in condition for allowance. Furthermore, any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although changes to the claims have been made, no acquiescence or estoppel is or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter.

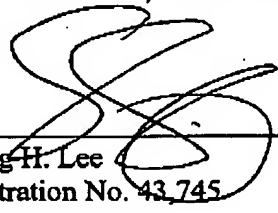
Applicants respectfully request that a Notice of Allowance be issued at the earliest opportunity. However, if the Examiner has any questions or concerns, she is invited to telephone Applicants' attorney of record so that extended prosecution of this application may be avoided.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 12-5-06

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